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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/242,202 11/01/99 NELSON

E 2026-4236US1

EXAMINER

HM22/0913

OFFICE OF TECHNOLOGY TRANSFER  
PATENT BRANCH  
NATIONAL INSTITUTES OF HEALTH  
6011 EXECUTIVE BOULEVARD SUITE 325  
ROCKVILLE MD 20852

I.L.D.

ART UNIT

PAPER NUMBER

1632

14

DATE MAILED:

09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/242,202

Applicant(s)

NELSON ET AL.

Examiner

Janice Li

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 November 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-51 and 60-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-51 and 60-65 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: *enclosure*.

### **DETAILED ACTION**

The preliminary amendment filed on Nov. 1, 1999 has been entered and assigned as Paper #6.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Misnumbered claims 8-69 have been renumbered as claims 7-65. A copy of renumbered claims has been enclosed with this Office action.

Claims 52-59 (original claims 55-62) have been canceled. Currently, claims 1-51, and 60-65 are pending in the application.

### ***Sequence Rule Compliance***

The specification and claims contain sequence disclosures (Claims 12, Figures 2-4) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2) but are not identified in the specification by sequence identifier numbers or present in the Sequence Listing. Applicant must provide sequence identifier where applicable, and if necessary a paper copy, a computer readable copy of the Sequence Listing and a statement that the content of the paper and computer readable copies are the same and; where

applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). A full response to this Office Action must include a complete response to the requirement for a Sequence Listing.

### ***Claim Objections***

Claims 4-13, 15, 20-22, 27-43, 46, and 61-65 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from any other multiple dependent claim. See MPEP § 608.01(n). For the purpose of an expedited prosecution, these claims have been treated on merits as if they recite proper dependency. Appropriate correction is required.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-33, 36-45, 60-65 are drawn to a humanized polynucleotide vector, a pharmaceutical composition comprising at least one of recited vector, a kit comprising the vector, and methods of making the vector and using such for eliciting a specific immune response in a mammal. Classified in class 435, subclass 320.1, and class 514, subclass 44.

II. Claims 34 and 35 are drawn to a host cell comprising a polynucleotide vector. Classified in class 424, subclass 93.21.

III. Claim 46 is drawn to an isolated antibody. Classified in class 530, subclass 387.1.

IV. Claims 47-51 are drawn to a sequence acceptance site. Classified in class 536, subclass 24.1.

2. The invention listed as groups I-IV do not relate to a single inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups II, III, IV differs from group I in that they are different products (a nucleic acid vector, a cell, an antibody, and a sequence acceptance site), having distinct structural differences. 37 CFR 1.475 (b) states "AN INTERNATIONAL OR A NATIONAL STAGE APPLICATION CONTAINING CLAIMS TO DIFFERENT CATEGORIES OF INVENTION WILL BE CONSIDERED TO HAVE UNITY OF INVENTION IF THE CLAIMS ARE DRAWN **ONLY TO ONE** OF THE FOLLOWING COMBINATIONS OF CATEGORIES: (1) A PRODUCT AND A PROCESS SPECIALLY ADAPTED FOR THE MANUFACTURE OF SAID PRODUCT; OR (2) A PRODUCT AND A PROCESS OF USE OF SAID PRODUCT; OR (3) A PRODUCT, A PROCESS SPECIALLY ADAPTED FOR THE MANUFACTURE OF THE SAID PRODUCT, AND A USE OF THE SAID PRODUCT; OR (4) A PROCESS AND AN APPARATUS OR MEANS SPECIFICALLY DESIGNED FOR CARRYING OUT THE SAID PROCESS; OR (5) A PRODUCT, A PROCESS SPECIALLY ADAPTED FOR THE MANUFACTURE OF THE SAID PRODUCT, AND AN APPARATUS OR MEANS SPECIFICALLY DESIGNED FOR CARRYING OUT THE SAID PROCESS." Since multiple products are claimed, unity of invention is lacking and restriction is required. The differences in the special technical features of the Inventions

I-IV are further underscored by their divergent classification and independent search criteria.

Furthermore, as cited in the International Preliminary Examination Report, Group III and IV are anticipated or obvious over the cited prior art of record. Applicants are advised to see 37 CFR 1.475 (a)-(d) for details. 37 CFR 1.475 (a) recites "AN INTERNATIONAL AND A NATIONAL STAGE APPLICATION SHALL RELATED TO ONE INVENTION ONLY OR TO A GROUP OF INVENTIONS SO LINKED AS TO FORM A SINGLE GENERAL INVENTIVE CONCEPT ('REQUIREMENT OF UNITY OF INVENTION'). WHERE A GROUP OF INVENTIONS IS CLAIMED IN AN APPLICATION, THE REQUIREMENT OF UNITY OF INVENTION SHALL BE FULFILLED ONLY WHEN THERE IS A TECHNICAL RELATIONSHIP AMONG THOSE INVENTIONS INVOLVING ONE OR MORE OF THE SAME OR CORRESPONDING SPECIAL TECHNICAL FEATURES." The expression "special technical features" shall mean those technical features that define a contribution, which **each** of the claimed inventions, considered **as a whole**, makes over the prior art. Consequently, the special technical feature of group III or IV does not provide a contribution over the prior art as a whole with groups I and II, so unity of invention is lacking.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen M Hauda can be reached on 703-305-6608. The fax numbers for the organization where this application or proceeding is assigned are 703-308-8724 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Kay Pinsky, whose telephone number is (703) 305-3553.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li  
Examiner  
Art Unit 1632

QJL  
September 10, 2001

  
ROBERT A. SCHWARTZMAN  
PRIMARY EXAMINER